REQUEST FOR WITHDRAWAL OF THE NOTICE OF WITHDRAWAL FROM ISSUE UNDER 37 C.F.R. § 1.313(b)

A Notice of Allowance of the pending claims was mailed on May 9, 2007, and the issue fee was paid. Then, improperly, a Notice of Withdrawal from Issue was mailed in this case on October 5, 2007. The Notice attempts to justify the withdrawal on the ground that the Office made a "mistake." In the Office Action dated November 26, 2007, the PTO asserts that the Action contains "new grounds of rejection."

Applicants strongly disagree with both contentions. There was no mistake, and there are no new grounds for rejection. The PTO cites no new references and presents no new arguments. It merely re-asserts references and arguments that have been previously presented and overcome. The same rejections have already been made by a competent Examiner and the Supervisory Primary Examiner. The responses, including amendments and remarks, were reviewed and accepted by the Examining team. Applicants understand that an anonymous reviewer intervened to cause the application to be withdrawn. This procedure violates the regulations and principles of compact prosecution. The PTO's actions in this regard impose an undue burden on the Applicants, deprive Applicants of finality, are unnecessarily dilatory, and do nothing to improve the quality of prosecution.

This application has been the victim of piecemeal prosecution. It has been allowed twice and has received nine Office Actions. Each time new objections have been raised, Applicants have addressed and overcome all objections and continued its prosecution. However, this time, there are no new grounds and there was no mistake, and the application should proceed directly to issuance.

In the Office Action, the PTO rejects claims under 35 U.S.C. § 103(a) as being unpatentable over Summerbell et al. (BMJ 317 1998 p. 1478-89) in view of Milk in Wikipedia, Dietary Supplement Fact Sheet: Calcium, and Ask A Scientist: IU. The same arguments have been presented previously and have been overcome. Summerbell formed the basis for rejections in Office Actions dated January 6, 2006 and June 21, 2006. Now, as in the previous Office Actions, the substance of the argument is that it would have been obvious to one of ordinary skill to formulate a high calcium diet for obese patients to achieve the beneficial effect of a reduction in body fat content. These rejections were overcome, as evidenced by the Office Action dated

December 18, 2006 allowing most claims and asserting no rejections based on Summerbell. The references Milk in Wikipedia, Dietary Supplement Fact Sheet: Calcium, and Ask A Scientist: IU are not prior art, because they were all accessed after the priority date for this application, and also because the websites are continually updated.

Furthermore, the PTO rejects claims under 35 U.S.C. § 112, second paragraph, arguing that the claim language "below ad lib" is indefinite. The term "below ad lib" was previously rejected for indefiniteness and the rejection was overcome. Applicants have previously amended independent claims 1, 50 and 61 to overcome indefiniteness rejections imposed by the PTO regarding this very claim element. These amendments were sufficient to overcome the PTO's concerns about indefiniteness. Now, the very language that Applicants added, and which the Examiner approved as sufficient to eliminate any issues under § 112 second paragraph, is again being rejected as indefinite for no new reason. There was no mistake and there are no new grounds for rejection. The lack of finality and the unnecessarily dilatory manner in which the PTO has handled this issue has deprived Applicants of its ability to obtain fair prosecution of its application, and has unnecessarily wasted time and money.

Applicants fail to see what mistake there was. The same rejections are being re-presented, and Applicants must re-present the same arguments to address the same issues when those arguments have already been considered and deemed persuasive by the PTO. The only result has been to needlessly delay Applicants' receipt of a patent for this invention.

The PTO has not made a mistake, and there are no new grounds for rejection. Therefore, Applicants submit that the Notice of Withdrawal from Issue was issued in error. Accordingly, Applicants request that the Notice of Withdrawal from Issue be withdrawn and that the application again be passed to issue.

In the alternative and in the interest of expediency, Applicants address the Examiner's arguments once again.

RESPONSE, IN THE ALTERNATIVE, TO THE OFFICE ACTION MAILED NOVEMBER 26, 2007

Currently pending are claims 1, 5, 6, 28-37, 41-44, 46-53, 55, 57, and 59-64. Please note that the list of pending claims in the Office Action is incorrect: the list should include pending claims 59 and 60 but does not; in addition, it should not include claim 65, but it does. Applicants request that the list of pending claims be corrected.

Claim Rejection – 35 U.S.C. § 103(a)

The Examiner has rejected the claims under 35 U.S.C. § 103(a) as being unpatentable over Summerbell et al. (BMJ 317 1998 p. 1478-89) in view of Milk in Wikipedia, Dietary Supplement Fact Sheet: Calcium, and Ask A Scientist: IU. Applicants traverse.

As stated previously in Applicant's response to the Office Action dated April 4, 2006, the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143. Each cited reference does not teach or expressly or impliedly suggest any of the limitations set forth in the present claims. There is no motivation to combine the reference with other knowledge. There would not be a reasonable expectation of success.

In addition, the Applicants previously submitted evidence showing the present invention's unexpected results, which has led to a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention leading to significant recognition and commercial success.

As set forth in the introduction, Summerbell tests diets with high compliance and hence good for weight loss. The study in Summerbell was designed to test the hypothesis that prescription of a simple and novel diet would result in higher levels of compliance and weight loss. In fact, Summerbell associates higher weight loss for the milk groups diet because that diet is "simple but much less boring and patients were more likely to comply with it" than with the conventional diet. Indeed, Summerbell is "not advocating milk only as a general long term reducing diet for obese outpatients, because in the long term it will cease to be novel and compliance will fall." Summerbell concludes that "[p]robably the best strategy is to rotate diets..." This statement would lead one away from the teaching of the present invention, which involves the use of sufficient amounts of dietary calcium or dairy, e.g., daily for a month or more. The point to extrapolate from Summberbell is that one could use any type of food regimen or diet so long as it is simple and less

boring to ensure compliance. Nowhere in Summerbell is it disclosed that calcium or dairy alone directly induces weight loss, as opposed to indirectly causing a dieter to loss weight by reducing overall caloric intake.

Furthermore, Summerbell does not disclose, teach or suggest administering calcium-containing products comprising therapeutically effective amounts of calcium and thereby inducing a metabolic change. The Examiner fundamentally mischaracterizes the language of the claims, disregarding the claim language "comprising therapeutically effective amounts of calcium . . . and thereby inducing a metabolic change . . ." When this language is considered, it is clear that the claims at issue are patentable over Summerbell, because Summerbell does not disclose, teach or suggest that therapeutically effective amounts of calcium induce the metabolic change. Indeed, Summerbell offers no basis for concluding that the weight loss is attributable to any of the numerous nutrients in milk, let alone calcium in particular. Instead, Summerbell teaches away from this conclusion by attributing the weight loss to the simplicity and novelty of the diet, and also by stating that the authors are "not advocating milk only as a general long term reducing diet for obese outpatients . . ."

The Examiner's calculations regarding the number of servings of dairy or the amount of calcium in Summerbell are irrelevant, and the Wikipedia citation is not prior art. As previously explained and repeated in prior responses, Summerbell's diet is based on following a simple and easy-to-adhere-to diet that is not boring and monotonous. Summerbell does not teach or suggest the claimed method involving calcium inducing a metabolic change. In addition, one skilled in the art would not modify Summerbell because there is no reasonable expectation of success, because Summerbell indicates that the milk-only diet "will cease to be novel and compliance will fall."

Furthermore, because Summerbell offers no basis for concluding that the weight loss is attributable to the calcium in milk, replacing milk with other calcium-containing foods could not be "an obvious expedient," contrary to the Examiner's argument.

No other references are cited to cure the above-noted defects in Summerbell. Accordingly, Applicants request that this rejection be withdrawn.

Claim Rejection – 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1, 5-6, 28-37, 41-44, 47-53, 57, and 59-64 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention. Applicants traverse.

Applicants have previously amended independent claims 1, 50 and 61 to overcome the Examiner's concern that "restricted caloric diet" is vague and subjective. In Applicants' response to the Office Action dated January 10, 2006, Applicants amended claims 1, 50 and 61 to include the term "below ad lib." In response to the Examiner's continued assertions of indefiniteness as expressed in the Office Action dated June 21, 2006, Applicants further amended the claims to include "in a range of about 200 to about 2500 kcal per day." These amendments were sufficient to overcome the Examiner's rejection for indefiniteness. Now, the very language that Applicants added, and which the Examiner approved as sufficient to eliminate any issues under § 112 second paragraph, is itself being rejected as indefinite.

The Examiner contends that "[i]n claims 1 and 61, the phrase 'below ad lib in a range of about 200 to about 2500 kcal per day' is unclear." The Examiner asks "[i]s the implication here that 'ad lib' is a caloric intake that can exceed the claimed range?" As argued previously, "ad lib" and "below ad lib" are well-defined terms that pose no issues under § 112 second paragraph. As set forth in the specification, the caloric intake of an individual may be unmodified or ad lib and it may be desirable to reduce the caloric intake of the individual as part of the dietary plan (e.g., page 9, lines 3-9). Ad lib is defined as "without restraint or limit" (Merriam-Webster Online Dictionary <http://www.m-w.com/cgi-bin/dictionary> visited January 11, 2008). It is commonly understood in the field of nutrition that there are two practices of energy intake, e.g., food, drinks or calories, either (1) ad lib or (2) restricted. Ad lib is a commonly used term that is understood to be the unrestricted intake of food or calories available to the point of satisfaction. Restricted diets may include a variety of diets, including for example, restricting caloric intake. As is readily apparent from the specification, the restriction of unmodified or ad lib caloric intake may be slight or more extensive based on whether the individual is maintaining or reducing body weight. Thus, the terms "ad lib" and "below ad lib" are sufficiently definite for the purposes of § 112, second paragraph.

Furthermore, Applicants submit that it is irrelevant whether "ad lib" can exceed the claimed range, because the claim recites "below ad lib." The claim makes clear that the claimed dosing is

both "below ad lib" and "in a range of about 200 to about 2500 kcal per day." Thus, the rejection for indefiniteness should be withdrawn.

Conclusion

The Notice of Withdrawal From Issuance should itself be withdrawn, and the patent should proceed directly to issuance. In the alternative, a new notice of allowance should be mailed.

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance indicating the allowability of claims 1, 5, 6, 28-37, 41-44, 46-53, 55, 57, and 59-64 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment to deposit account no. 22-0261.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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